

### **REMARKS**

The original application was filed with Claims 1-56. Claims 1-17 and 34-56 were cancelled in a Preliminary Amendment filed on October 4, 2001. Claims 57 – 65 were added to the application in the same Preliminary Amendment and have since been withdrawn from consideration as drawn to a non-elected invention. Claims 57 – 65 have been cancelled in the present Reply. Claims 18 – 33 are currently pending and at issue. Of the claims remaining, Claims 18, 20, 22, 26-29 and 31 have been amended to address issues raised in the present PTO Action.

Claims 18 -33 stand initially rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent No. 3,780,308 to Nablo (hereinafter “Nablo”). Applicants respectfully traverse the rejection and request reconsideration in light of the above-amendments and the arguments set forth below.

#### **103 Rejection Requirements**

In order to support a conclusion that a claim is directed to obvious subject matter, the cited references must impliedly suggest the invention *described by the claim*, or the Examiner must present a convincing line of reasoning as to why an artisan would have found *the claimed invention* obvious in light of the teachings of the cited references. See Ex Parte Clapp, 227 U.S.P.Q. 972 (PTO Bd. App. 1985). “[T]he mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.” In re Laskowski et. al., 10 U.S.P.Q. 2d 1397, 1398, (Fed. Cir. 1989), citing, In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). In discussing the mandate of 35 U.S.C. §103, the Federal Circuit holds “it is the invention as a whole that must be considered in obviousness determinations. The invention as a whole embraces the structure, its properties *and the problem it solves*.”[Emphasis added]. In re Wright, 6 U.S.P.Q. 2d 1959 (Fed. Cir. 1988). It is not enough to just find components in the prior art.

On that point, the Federal Circuit has noted:

[I]t is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious . . . . [o]ne cannot

use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

*In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

Unless the references suggest the particular combination themselves, they cannot show the actual invention was obvious. *In re Mahurkar Patent Litigation*, 831 F.Supp. 1354, 1374, 28 USPQ2d 1801, 1817 (N.D. Ill. 1993). The decomposition of an invention “into its constituent elements, finding each element in the prior art, and then claiming that it is easy to reassemble these elements into the invention, is a forbidden *ex post* analysis.” *Id.*

#### Claim Amendment

Claim 18 has been amended to clarify language used to describe the field used to sterilize components. Previously, the pending claims referred to the field as an “active sterile field.” Independent Claim 18 now refers to the field as a “controlled sterilizing field.” The amendment merely clarifies that the active sterile field must be suitable to sterilize component surfaces, not just be sterile itself. It also emphasizes that the field must be controlled. The control feature distinguishes over by-products of the sterilizing effort, e.g., ozone creation and stray X-rays.

The claim amendment merely makes explicit that which is implicit. For example, at the low energies claimed, 50 to 150 KeV, the resulting electron beam is maintained at about two inches in diameter. Within that two inch diameter, penetration of component surfaces is intentionally minimal. Beyond the two inch range the sterilizing effect of the beam becomes almost nonexistent. These limitations are well supported and explained in the present application—e.g., see page 7, lines 14-15 (“Tube 54 is preferably about 5 cm (2”) from the area in which an active sterile field is desired and operates at about 60 KeV.”); page 7, lines 17-18 (“Tube 54 creates the spherical-shaped e-beam field 60 having approximately a two-inch diameter.”); page 10, lines 7-9 (“Upon reaching the dispensing valve 92, as shown at point (C), the inlet port 97 and membrane are held within the sterile field 60 aligned with dispensing valve 92 to effect sterilization of the outer surfaces.”).

Claims 20, 22, 26-29 and 31 have been amended to reflect the changes to independent Claim 18. Claim 27 has also been amended to remove the indefinite term “large” as required.

U.S. Patent No. 3,780,308 to Nablo

Nablo discloses an aseptic filling process and apparatus. Specifically, Nablo discloses a surface sterilization process for packaging articles or containers **7**. The containers **7**, as shown in Figures 5a and 5b, are irradiated under sterilizing head **A** before moving to the filler spout being irradiated by dual sterilizing heads **B**. Nablo states that the “system is used to maintain the surface of the filler spout **3'** in aseptic condition while in the retracted position on each operation.” (Col. 6, lines 39-42). During the transfer of the containers **7** from head **A** to heads **B**, the container **7** is not within a sterilizing field created by either sterilizing head. Instead, the container **7** is exposed to the ambient environment within zone **4**. Nablo does not disclose this zone **4** to be a sterilizing field.

Nablo states, “Aseptic conditions in the working volume **4** are accomplished by the use of high efficiency particle filtration of the air..., so that a positive pressure of sterile air is maintained in zone **4**.” (Col. 6, lines 54-60). Nablo also discloses that the air may be sterilized by using, for example, an irradiating head “to treat air driven into region **4** during each operation of filler head **3'**.” (Col. 6, lines 60-64).

The present Office Action points to Nablo's disclosure of ozone creation to effect sterilization. However, free ozone (O<sub>3</sub>) is a by-product of the electron beam under aerobic conditions. The resulting ozone concentration is unknown, unpredictable and uncontrollable. Accordingly, ozone used in this manner is an unreliable and potentially ineffective sterilization source. It by no means qualifies as a “controlled sterilizing field” as required by the present claims.

Further to the point made about Nablo disclosing the use of a thin lead shield to enclose the area **4** as proof of the entire zone being active, Applicants disagree. The use of shielding is required due to the production of stray X-rays during electron beam sterilization. Such X-rays, while potentially sterilizing, are unpredictably created and lack the density and direction required for effective sterilization of component surfaces. However, the mere threat of X-ray creation would warrant shielding of the sterilization area, even if the entire area was not active.

Additionally, as noted in previous correspondence, Nablo discloses maintaining the “dispensing” port of the bulk container in a sterile field. While the present invention does this as

well during filling of containers, it is the filling port of the container itself which must be maintained in the active sterile field during filling of the container. Maintaining the container filling port within a purported sterile or aseptic environment is not sufficient for purposes of the present invention, and fails to properly render obvious the present claims.

Accordingly, maintaining the container port within the controlled sterilizing field while filling the container with a bulk fluid is an important step in the sterilization process. Nablo places a greater importance on maintaining the dispensing port of the bulk container within the field only when retracted---that is, when it is not dispensing liquid. The potential result is contamination of the container filling port, a significant undesirable occurrence for medical containers such as IV bags, drug vials, and the like.

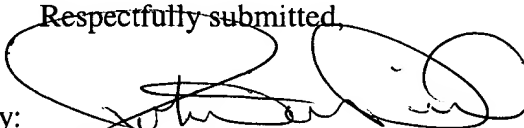
Accordingly, the Applicants traverse the Examiner's rejection of independent Claim 18. All the remaining claims are dependent upon independent Claim 18. Each dependent claim merely adds a further limitation to this independent claim. As Claim 18 is in condition for allowance, the dependent claims should likewise be considered allowable. Accordingly, reconsideration is respectfully requested and a notice to that effect is earnestly sought at the examiner's earliest convenience.

### CONCLUSION

Claims 1-56 were originally pending in the present application. Claims 1-17 and 34-56 were cancelled in a Preliminary Amendment filed on October 4, 2001. Claims 57 – 65 were added, subsequently withdrawn from consideration, and now stand cancelled from the present application. Claims 18 – 33 are currently pending and at issue. Of these remaining claims, Claims 18, 20, 22, 26-29 and 31 have been amended to address issues from the December 7, 2005 Office Action. The Action has initially rejected each of these claims under 35 U.S.C. 103 and 112. Applicants have amended the referenced claims to clarify matters where necessary. In light of the amendments and the above-remarks, Applicants believe all considered claims are now in condition for allowance. Reconsideration of these claims is respectfully requested.

If it would expedite the progress of this Application through the examination process, the Examiner is authorized to call the undersigned attorney.

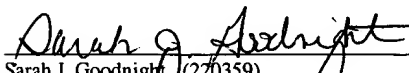
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